

1                    2.    (Amended) Use of the test as claimed in claim 1 wherein  
2    the method comprise the steps of:

- 3                    a)    taking a sample from each participant or potential participant  
4                    in a clinical drug trial,  
5                    b)    screening the samples for the genetic basis of Gilbert's  
6                    Syndrome,  
7                    c)    identifying such participants having the genetic basis of  
8                    Gilbert's Syndrome, and  
9                    d)    proceeding with the clinical drug trial based on the  
10                   knowledge of such participants possessing or not possessing  
11                   the genetic basis of Gilbert's Syndrome.
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1                    3.    (Twice Amended) Use of the test as claimed in claim 1  
2    wherein the sample is chosen from blood, buccal smear or any other sample  
3    containing DNA from the participants or potential participants.

1                    4.    (Twice Amended) Use of the test as claimed in claim 1  
2    wherein the method further comprises the step of eliminating participants having  
3    the genetic basis of Gilbert's Syndrome from the clinical drug trial.

1                    5.    (Twice Amended) Use of the test as claimed in claim 1  
2    wherein the method further comprises the step of selecting only participants  
3    having the genetic basis for Gilbert's Syndrome for the clinical drug trial.

1                   6. (Twice Amended) Use of the test as claimed in claim 1  
2 further comprising the step of interpreting the results of the clinical drug trial  
3 based on the knowledge that certain participants have the genetic basis of  
4 Gilbert's Syndrome as distinguished from participants adversely affected by the  
5 drug.

1                   7. (Twice Amended) Use of the test as claimed in claim 1  
2 wherein the method comprises the steps of:

- 3                   a) isolating DNA from each sample,  
4                   b) amplifying the DNA inner region indicating the genetic basis  
5                   for Gilbert's Syndrome,  
6                   c) isolating amplified DNA fragments, and  
7                   d) identifying participants having the genetic basis of Gilbert's  
8                   Syndrome.

1                   8. (Twice Amended) Use of the test as claimed in claim 7  
2 wherein the DNA is amplified using the polymerase chain reaction (PCR) using  
3 a radioactively labeled pair of nucleotide primers.

1                   9. (Twice Amended) Use of the test as claimed in claim 7  
2 wherein the DNA region indicating the genetic basis of Gilbert's Syndrome is  
3 the gene encoding UDP-glucuronosyltransferase (UGT).

1 10. (Twice Amended) Use of the test as claimed in claim 7  
2 wherein the DNA to be amplified is in an upstream promoter region of the UGT  
3 1\*1 exon 1.

C2  
cont  
1 11. (Twice Amended) Use of the test as claimed in claims 7  
2 wherein the DNA to be amplified includes the regions between -35 and -55  
3 nucleotides at the 5' end of UGT 1\*1 exon.

1 12. (Twice Amended) A kit for screening participants or potential  
2 participants in clinical drug trials, wherein the kit comprises primers for  
3 amplifying DNA in the region of the genome indicating the genetic basis of  
4 Gilbert's Syndrome.

1 13. (Twice Amended) Primers for use of the test as claimed in  
2 claim 1 including primer pairs, AB or CD as follows:

3 A/B: (A,5' - AAGTGAAGTCCCTGCTACCTT-3' (SEQ ID NO:1),

4 B,5' -CCACTGGATCAACAGTATCT-3' (SEQ ID NO:2) or

5 C/D: (C,5' -GTCACGTGACACAGTCAAAC-3' (SEQ ID NO:3);

6 D 5' -TTTGCTCCTGCCAGAGGTT-3' (SEQ ID NO:4)).

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**A. Brief Summary of the Present Invention**

The present invention relates to a method for improving the efficacy of clinical drug trials. Specifically, the method of the present invention can be used to screen samples containing DNA from potential participants or